REMARKS

After entry of this Amendment, claims 1, 5, 9, 51 and 59 will be pending in this application.

The Examiner noted that claims 5 and 59 incorrectly refer to "an immunogenic components" rather than to "an immunogenic component." Claims 5 and 59 have been amended to refer to "an immunogenic component." This Amendment does not add any new matter to the application.

Rejection Under 35 U.S.C. § 112, ¶ 2

The Examiner has rejected claims 1, 5, 9, 51 and 59 under 35 U.S.C. § 112, ¶ 2 as indefinite. The Examiner alleges that the phrases "wherein increased or decreased expression [...] aids in the identification of the infecting pathogen" or "wherein increased or decreased expression [...] aids in diagnosis of infection by the pathogen" are vague and indefinite because"[i]t is unclear what degree of increased or decreased expression is required for such aiding as one skilled in the art would realize that some variation is likely due to experimental variation or background noise."

Applicants respectfully traverse. A person of skill in the art reading the claims in light of the specification would clearly understand the claim language, and would be able to determine the metes and bounds of the claimed invention. Applicants respectfully submit that once a pathogen-specific gene is identified, a person of skill in the art could determine using only routine experimentation whether the expression of that pathogen-specific gene is increased or decreased relative to the expression of the same gene in a reference gene expression profile, or whether a variation in the expression levels of a pathogen-specific gene is due to experimental variation or background noise. Applicants submit that there are standard methods which are routinely used by persons of skill in the art to determine whether variations in the expression of a particular gene represent an increase or decrease in expression, rather than just experimental variation or background noise. The specification teaches that a pathogen-specific gene is one whose expression is increased or decreased by a pathogen (*e.g.*, page 5, lines 20-23 and page 15, line 28 through page 16, line 2). Therefore, the increased or decreased expression of a pathogen-specific gene in dendritic cells relative to expression of the pathogen-specific gene in a reference gene expression profile aids in the identification/diagnosis of a pathogen. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Rejection Under 35 U.S.C. § 103

The Examiner has rejected claims 1, 5, 9, 51 and 59 under 35 U.S.C. § 103 as unpatentable over Cummings *et al.* (Genomics, 6(5):513-525; Sept-Oct 2000; "Cummings") in view of Exley *et al.* (US 2002/0164331; "Exley").

Applicants traverse. Cummings does not disclose or suggest the claimed methods of aiding in the identification or diagnosis of pathogens based in the expression of pathogen-specific genes in dendritic cells. The Examiner argues that the teachings of Exley can be combined with the teachings of Cummings to arrive at the claimed invention. However, the teachings of Exley cannot be combined with the teachings of Cummings to arrive at the claimed invention. First, there would have been no motivation to combine the teachings of Exley and Cummings. Second, even if the teachings of Exley and Cummings were combined, the claims would not be obvious since neither reference teaches the identification of pathogen-specific genes from dendritic cells.

Exley relates to compounds and methods for expanding specific subpopulations of T cells, and diagnostic and therapeutic applications for such compounds and methods (Exley, abstract). Applicants respectfully submit that T cells are not dendritic cells. As submitted in Applicants' previous reply, dendritic cells are specific types of cells in the immune system. More particularly, as defined in the specification, dendritic cells are antigen presenting cells which reside in most tissues and which trigger a T cell adaptive immune response (page 1, lines 14-20).

Applicants regret any confusion which might have been caused by a previously submitted definition of the term "dendritic cell" from an online medical dictionary which erroneously suggested that dendritic cells are T cells. The previously submitted definition of "dendritic cell" can be found in Exhibit A. Applicants submit that the definition of "dendritic cell" provided in part (3) of Exhibit A is overly broad, and inconsistent with the use of the term in the specification (see, page 1, lines 14-20). Applicants are hereby submitting as Exhibit B, excerpts from the textbook Cellular and Molecular Immunology, 4th Edition. This textbook provides a more relevant definition of "dendritic cells" which is consistent with the use of the term in the specification. For example, on page 24, dendritic cells are defined as "accessory cells that play important roles in the induction of T lymphocyte responses to protein antigens." Further, on pages 84 and 86, the textbook again points out that dendritic cells are competent at presenting antigen to T cells. Thus, the term "dendritic

cells" is commonly understood to refer to specific types of immune cells which present antigens to T cells.

Further, even if T cells were dendritic cells, which they are not, the combined teachings of Cummings and Exley would not render obvious the claimed invention. Applicants respectfully traverse the Examiner's description of the teachings of Exley. Exley does not teach or suggest the identification of pathogen-specific genes from T cells.

The Examiner states that Exley described diagnostic assays involving T cells. However, the diagnostic assays described in Exley are based on the detection of a specific subpopulation of T cells, not in the identification of pathogen-specific genes in either T cells or dendritic cells.

The Examiner states that Exley describes using immature and mature dendritic cells in various experiments including DNA microarrays. However, Exley does not disclose or suggest the use of DNA microarrays to determine the expression of pathogen-specific genes in T cells or dendritic cells. Instead, Exley only describes the use of dendritic cells to activate T cells which are then used in DNA microarrays to identify genes involved in T cell activation (see Exley, Example 13).

The Examiner also states that Exley describes contacting T cells with antigens or antigen presenting cells (such as dendritic cells), wherein the antigen is a pathogen. However, Exley does not teach contacting T cells with antigens (such as pathogens) to identify pathogen-specific genes. Rather, Exley teaches contacting T cells with antigen or antigen presenting cells to increase the size of a specific subpopulation of T cells. (The fact that Exley discloses the use of dendritic cells to activate T cells supports Applicants' position that denderitic cells are not T cells.)

Finally, the Examiner argues that because Exley mentions that there is a need to specifically monitor T cells in mammals for infections, a person of skill in the art would be motivated to combine the teachings of Exley with the teachings of Cummings. Applicants disagree. There is nothing in Exley that would link its teachings to the teachings of Cummings. Nothing in Exley discloses or suggests the use of T cells or dendritic cells to identify pathogen-specific genes, and the use of pathogen-specific genes to diagnose or identify pathogens. Thus, there would be no motivation to combine the teachings of Exley with the teachings of Cummings.

Further, even if the teachings of Exley and Cummings were combined, the claims of the instant patent would not be rendered obvious since neither reference discloses the use of dendritic cells to identify pathogen-specific genes which could be subsequently used to diagnose/identify pathogens. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

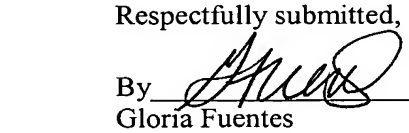
Conclusion

In view of the above amendment and argument, Applicants believe the pending application is in condition for allowance, and respectively request that this application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, from which the undersigned is authorized to draw, under Order No. WIBL-P01-548.

Dated: February 1, 2005

Respectfully submitted,

By 

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